Vaccine and Treatment Evaluation Units (VTEUs): Evaluation of Control Measures Against Infectious Diseases Other than AIDS
RFP NIH-NIAID-DMID-08-03

SECTION M – EVALUATION FACTORS FOR AWARD

1. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: technical, cost, past performance and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, past performance, cost/price and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

2. HUMAN SUBJECT EVALUATION

This research project involves human subjects. NIH Policy requires:

a) Protection of Human Subjects from Research Risks

The offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation, or provide sufficient information on the research subjects to allow a determination by NIAID that a designated exemption is appropriate.

If you claim that this research should be considered exempt from coverage by the Federal Regulations at 45 CFR 46, the proposal should address why you believe it is exempt, and under which exemption it applies.

The reviewers will evaluate the proposal with regard to four issues: Risks to Human Subjects, Adequacy of Protection Against Risks, Potential Benefits of the Proposed Research to the Subjects and Others, and Importance of the Knowledge to be Gained. See Section L for a complete discussion of what is required to be addressed for each of these issues. Based on the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the protections described against risk to human subjects or no discussion is found regarding protections against risk to human subjects) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government elects to conduct discussions and includes your proposal in the competitive range, you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the protection of human subjects from research risks is still found to be unacceptable, then your proposal may not be considered further for award.

b) **Data and Safety Monitoring**

The offeror's proposal must include a general description of the Data and Safety Monitoring Plan for all clinical trials. The principles of data and safety monitoring require that all biomedical and behavioral clinical trails be monitored to ensure the safe and effective conduct of human subjects research, and to recommend conclusion of the trial when significant benefits or risks are identified or if it is unlikely that the trial can be concluded successfully. Risks associated with participation in research must be minimized to the extent practical and the method and degree of monitoring should be commensurate with risk. Additionally, all plans must include procedures for adverse event reporting. ***For clinical trials and other trials for which the risks and complexities justify it, the Safety Oversight Structure shall be a Data and Safety Monitoring Board (DSMB); for most Phase 1 and Phase 2 clinical trials, the Safety Oversight Structure shall be a Safety Monitoring Committee (SMC).*** The reviewers will rely on the Statement of Work and Section L in the solicitation, as well as any further technical evaluation criteria in this Section M, as applicable, for the solicitation's specific requirements for data and safety monitoring.

As a part of the evaluation for proposals, the reviewers will consider the acceptability of the proposed data and safety monitoring plan with respect to the potential risks to human participants, complexity of study design, and methods for data analysis. Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the adequacy of the monitoring plan or no discussion can be found regarding the proposed monitoring plans) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government elects to conduct discussions and includes your proposal in the competitive range, you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for data and safety monitoring is still found to be unacceptable, then your proposal may not be considered further for award.

c) **Women and Minorities**

Women and members of minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. In addition, for NIH-Defined Phase III clinical trials, all proposals and/or protocols

must provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, Definitions - Significant Difference) by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable, unless the Government has specified that this solicitation involves a sex/gender specific study or a single or limited number of minority population groups. The proposal also must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, OR

- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups (representation of sex/gender and/or racial/ethnic groups as subject selection criterion is not required; however, inclusion and analyses are encouraged), OR

- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Also, the proposal must address the proposed outreach programs for recruiting women and minorities as participants. Reviewers will consider the areas covered here and in Section L of the solicitation in narrative form in their evaluation. Some of the issues they will evaluate include:

- whether the plan proposed includes minorities and both genders in adequate representation
- how the offeror addresses the inclusion of women and members of minority groups and their subpopulations in the development of a proposal that is appropriate to the scientific objectives of the solicitation
- the description of the proposed study populations in terms of sex/gender and racial/ethnic groups and the rationale for selection of such subjects
- if exclusion is proposed, that the rationale is appropriate with respect to the health of the subjects and/or to the purpose of the research.
- In addition, for gender exclusion, the reviewers will examine the rationale to determine if it is because:

    - the purpose of the research constrains the offeror's selection of study participants by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or
    - overriding factors dictate selection of subjects); or
    - gender representation of specimens or existing datasets cannot be accurately determined, and this does not compromise the scientific objectives of the research.

- For minority group exclusion, the reviewers will examine the rationale to determine if those minority groups are excluded because:

  - inclusion of those groups would be inappropriate with respect to their health; or
  - inclusion of those groups would be inappropriate with respect to the purpose of the research.

- For NIH-defined Phase III clinical trials, reviewers will also consider whether there is an adequate description of plans to conduct analyses to detect significant differences of clinical or public health importance in intervention effect(s) by sex/gender and/or racial ethnic subgroups when the intervention effect(s) is expected in the primary analyses, or if there is an adequate description of plans to conduct valid analyses of the intervention effect in subgroups when the intervention effect(s) is <u>not</u> expected in the primary analyses.

If you determine that inclusion of women and minority populations is not feasible, you must submit a detailed rationale and justification for exclusion of one or both groups from the study population with the technical proposal. The Government will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research.

Based on the evaluation of the response to this criterion, this section of the proposal may be rated “unacceptable” (i.e., no discussion can be found regarding the proposed gender/minority inclusion plans, or concerns are identified as to the gender or minority representation, or the proposal does not adequately address limited representation of one gender or minority; or the plan is not in accordance with NIH policy guidelines) or “acceptable.” See Section L of the solicitation for the requirements of women/minorities inclusion. If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government elects to conduct negotiations and includes your proposal in the competitive range, you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the inclusion/exclusion of women and minorities is still found to be unacceptable, then your proposal may not be considered further for award.

d) **Children**

Children (i.e. individuals under the age of 21) must be included in all human subject research unless there are clear and compelling reasons not to include them.

Your proposal must include a description of plans for including children. If you plan to exclude children from the required research, your proposal must present an acceptable justification for the exclusion. If you determine that exclusion of a specific age range of child is appropriate, your proposal must also address the rationale for such exclusion. Also, the plan must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the

inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation. Also, see Section L of the solicitation for further specific requirements on inclusion of children.

Based on the reviewers' evaluation of the offeror's response, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed inclusion plans for children; or concerns are identified as to the offeror's response regarding the inclusion of children; or the plan is not in accordance wit h NIH policy guidelines) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government elects to conduct negotiations and includes your proposal in the competitive range, you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the inclusion of children is still found to be unacceptable, then your proposal may not be considered further for award.

3. **EVALUATION OF DATA SHARING PLAN**

The offeror's plan for the sharing of final research data shall be assessed for appropriateness and adequacy. If your proposal does not include a plan or if the plan in your proposal is considered "unacceptable," and the Government elects to conduct negotiations and includes your proposal in the competitive range, you will be afforded the opportunity to further discuss, clarify or modify your data sharing plan during discussions and in your Final Proposal Revision (FPR). If your data sharing plan is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

4. **EVALUATION OF PLAN FOR SHARING MODEL ORGANISMS FOR BIOMEDICAL RESEARCH**

The Offeror's proposal must address the plans for sharing model organisms, OR state appropriate reasons why such sharing is restricted or not possible. Offerors must also address as part of the sharing plan if, or how, they will exercise their intellectual property rights while making model organisms and research resources available to the broader scientific community. The discussion areas regarding intellectual property outlined in Section L should be addressed.

If your proposal does not include a plan, appropriate reasons for restricting sharing, or, if the plan in your proposal is considered "unacceptable," and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your plan for sharing model organisms during discussions and in your Final Proposal Revision (FPR). If your plan for sharing model organisms is still considered "unacceptable," or your justification for restricting sharing is still considered inappropriate by the Government after discussions, your proposal may not be considered further for award. The following web site provides guidance on sharing model organisms and additional information about this policy: http://grants.nih.gov/grants/policy/model_organism/index.htm.

5. **TECHNICAL EVALUATION CRITERIA**

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

CRITERA	**WEIGHT**
A. **TECHNICAL PLAN/APPROACH**	**35**

The offeror's overall understanding of the objectives and requirements of the RFP, ability to identify problems and suggest solutions, and the ability to enhance the achievement of the scientific goals of the overall program will be evaluated for the following elements.

1. Clinical Trials, Clinical Studies and Other Evaluations and Analyses: Ability to design and conduct clinical trials and clinical studies, as well as other evaluations and analyses, as evidenced by the soundness, appropriateness, adequacy and feasibility of the scientific, technical and operational plans for the three case studies:

    a. Case Study 1: Phase 1 Clinical Trial of West Nile Virus Vaccine
    b. Case Study 2: Phase 3 Clinical Trial of an Inactivated Influenza Vaccine
    c. Case Study 3: Phase 1 Clinical Trial of a Meningitis Vaccine

2. Study Populations and Enrollment Requirements:

    a. General Population:

        1) Adequacy of documentation with respect to access to the number and type of populations required to serve as study participants, and ability to recruit and retain study participants from the general population;
        2) Ability to identify anticipated recruitment and retention problems and difficulties that may arise and adequacy of proposed approaches to overcome or minimize anticipated problems and difficulties.

b. Additional Populations:

1) Adequacy of documentation with respect to access to the scope of additional populations to serve as study participants, including women of child-bearing age, pregnant women, immunocompromised populations, non-U.S. populations, and populations with underlying medical conditions;
2) Ability to recruit and retain additional study populations; and;
3) Ability to identify anticipated recruitment and retention problems and difficulties that may arise and adequacy of proposed approaches to overcome or minimize anticipated problems and difficulties.

3. Demonstrated ability to adhere to Good Clinical Practices (GCP).

B. PROTOCOL IMPLEMENTATION AND OVERSIGHT 15

Ability to implement and provide oversight for clinical trials, clinical studies and other evaluations/analyses as evidenced by the appropriateness and adequacy of proposed plans for the following:

1. Internal procedures for assuring safety oversight for study participants and compliance with all safety guidelines and regulations at the VTEU institution and all affiliated clinical sites;
2. System for reporting data and information from safety and efficacy testing of candidate vaccines and therapeutics;
3. System of records for all documentation required for the conduct of clinical trials and clinical studies;
4. Plans for accommodating clinical site monitoring activities and developing and implementing remedial actions to address deficiencies and problems identified through the clinical site monitoring process;
5. Procedures for receiving, labeling, storing and tracking study products and for monitoring storage conditions, and sample Standard Operating Procedure for inventory control system;
6. Procedures for classification, labeling, documentation, shipping and tracking of clinical specimens and demonstrate ability to meet requirements of the International Transport Association for shipping of dangerous goods; and
7. Quality assurance/quality control plan, including data management and quality control systems/procedures and plans to accommodate independent auditors.

C. **PERSONNEL** **20**

1. Principal Investigator: Appropriateness and adequacy of the training, experience, expertise and level of effort of the proposed Principal Investigator with respect to the following:

    a. The design, conduct and analysis of clinical trials, clinical studies and other evaluations and analyses for testing the safety and efficacy of vaccine and therapeutic candidates for infectious diseases;
    b. The management and oversight of clinical trials and clinical studies, including multi-site trials and studies, with respect to ensuring adherence to Federal regulations, Good Clinical Practice, and protocol-specific requirements for the conduct of research involving human subjects, including the development and implementation of standard operating procedures and plans for quality assurance/quality control, the identification of performance problems and deficiencies, and the implementation of remedial actions to address performance problems and deficiencies; and
    c. Collaborating with industry and clinical research support services contractors with respect to study design, statistical analysis, preparation of and reporting study data for Investigational New Drug (IND) applications, data management and quality control, and clinical site monitoring.
    d. Documented active physician's licensure in the United States.

2. Other Scientific and Technical Personnel: Appropriateness and adequacy of the training, experience, expertise and level of effort of other proposed scientific and technical personnel of the offeror and all proposed subcontractors, including the adequacy of the proposed mix of staff, expertise, experience, and training to carry out contract requirements with respect to the following:

    a. The conduct of clinical trials and clinical studies of candidate vaccines and therapeutics for infectious diseases in accordance with Federal regulatory requirements, protocol-specific requirements, and Good Clinical Practice;
    b. The receipt, packaging, distribution and tracking of study products;
    c. The collection and processing of clinical specimens and the conduct of protocol relevant tests to determine patient eligibility and safety evaluations;
    d. The packaging, labeling and transport of clinical specimens; and
    e. Data entry, management and quality control.

D. FACILITIES AND OTHER RESOURCES 20

1. The availability, adequacy and suitability of the clinical research facilities, equipment and other resources of the Offeror and all proposed subcontractors for the conduct of clinical trials, clinical studies and other evaluations and analyses in accordance with Federal regulatory requirements and guidelines, including Good Clinical Practice, NIH, NIAID and DMID policies and procedures, and the scope and requirements of the RFP. This includes:

    a. Outpatient and inpatient clinical research facilities;
    b. Clinical laboratory and clinical research laboratory facilities;
    c. Research pharmacy facilities; and
    d. General clinical research facilities.

2. Adequacy and appropriateness of plans for accessing the facilities and other resources of VTEU-affiliated clinical sites and plans for adding or deleting facilities as necessary due to progress or performance issues that arise during the course of the contract.

E. PROJECT MANAGEMENT 10

1. Overall Project Management
    a. Adequacy of the plans for the staffing, organization, distribution of responsibilities, leadership and lines of authority for carrying out contract requirements;
    b. Suitability of systems proposed for tracking contract activities and monitoring progress, timelines and budgets;
    c. Suitability of plan for how the Principal Investigator will communicate with the Project Officer and the Contracting Officer, as well as established lines of communication among all performance sites and activities; and
    d. Suitability of the plan for how the Contractor will safeguard data and materials provided by third parties or the Government, as well as data generated during the contract.

2. Subcontract Acquisition and Management
    Adequacy and suitability of subcontract acquisition and management with respect to:

    a. Plan for soliciting, evaluating, awarding and managing subcontracts;
    b. Plans and methods to assess subcontractor performance, identify performance problems and approaches for their remediation, including non-compliance with subcontract terms and conditions, and implement corrective actions when necessary; and
    c. Experience and expertise of proposed staff responsible for the management of subcontracts.

TOTAL 100

6. PAST PERFORMANCE FACTOR

An evaluation of offerors' past performance information will be conducted prior to any communications with offerors leading to establishment of the competitive range. However, this evaluation will not be conducted on any offeror whose proposal will not be admitted to the competitive range on the basis of the results of the evaluation of factors other than past performance.

The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be a product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

7. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

SDB participation will not be scored, but the Government's conclusions about overall commitment and realism of the offeror's SDB Participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

(a) Extent to which SDB concerns are specifically identified
(b) Complexity and variety of the work SDB concerns are to perform
(c) Extent of participation of SDB concerns in terms of the value of the total acquisition.